

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

12

EUROPEAN PATENT APPLICATION

21 Application number: 87107700.4

51 Int. Cl.: **A 61 M 5/14**

22 Date of filing: 26.05.87

30 Priority: 29.05.86 JP 124337/86

71 Applicant: Terumo Kabushiki Kaisha, No. 44-1, Hatagaya 2-chome Shibuya-ku, Tokyo 151 (JP)

43 Date of publication of application: 02.12.87
Bulletin 87/49

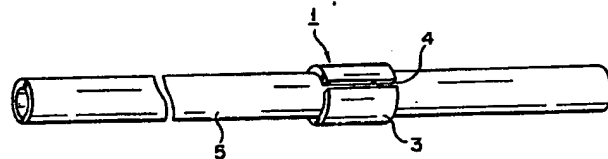
72 Inventor: Moriuchi, Yousuke, 4020-18, Mannocharashinden, Fujinomiya-shi Shizuoka-ken (JP)
 Inventor: Ishida, Toshinobu, 1568-6, Koizumi, Fujinomiya-shi Shizuoka-ken (JP)
 Inventor: Kousai, Tadashi, 2517, Ohmiya, Fujinomiya-shi Shizuoka-ken (JP)

84 Designated Contracting States: BE DE FR GB IT SE

74 Representative: Henkel, Feiler, Hänzle & Partner, Möhlstrasse 37, D-8000 München 80 (DE)

54 Catheter-securing member and catheter assembly mounted with the same.

57 A catheter-securing member (1) for holding and securing a catheter body (5) to a surface portion of human skin, without causing the catheter body (5) to be bent or reducing the diameter of the inner passage of the catheter body. This catheter-securing member (1) comprises a cylindrical body (3) for allowing the catheter body (5) to be slidably inserted therein, and a slit (4) is provided along the axial direction of the cylindrical body.



EP 0 247 590 A2

- 1 -

Catheter-securing member and catheter
assembly mounted with the same

5 The present invention relates to a catheter-securing member for securing in place a catheter to be indwelled in a human body for a long period of time, and a catheter assembly mounted with the catheter-securing member.

5 An intravenous catheter (to be referred to hereinafter as an IVH catheter) is widely used for high caloric fluid therapy. Other various catheters have been also used for long-term indwelling in a human body (e.g., in a vein).

10 A distal portion of the IVH catheter or the like is inserted into a vein by using, for example, the hollow needle method or the cut-down method. The part of the catheter outside of the body needs be secured in place, to avoid being accidentally moved. When such a catheter is indwelled in the body, a sepsis may occur as a complication. It is said that the cause of the sepsis is bacteria entering the body from the outside of the catheter, and that the rate of occurrence of
15 the sepsis increases when the catheter is not secured firmly to the body.

25 Conventional methods of securing the catheter are: securing the part of the catheter outside of the body by using surgical tape; forming a subcutaneous tunnel and inserting the catheter with a Dacron cuff thereinto;

and securing in place by suturing, with a ligature, the portion of the catheter outside of the body in the skin. In the method using the surgical tape, the catheter can still be easily moved, and therefore this method is not reliable. In the method of forming the subcutaneous tunnel, the catheter can be secured firmly in place. However, this operation is too complicated to be widely employed. Since a catheter of this type, e.g., an IVH catheter is normally indwelled for one or two weeks, the method of suturing the catheter in the skin by means of a ligature is widely employed as an easy-to-perform and reliable method.

However, using this method, the catheter may be broken at the portion tied by the ligature, or the cavity of the catheter may become so narrowed that a transfusion liquid cannot be supplied into the catheter at a predetermined flow rate.

It is an object of the present invention to solve the conventional problems described above and to provide a catheter which will not be broken at a portion tied by a ligature, and a cavity thereof not be narrowed, and hence a transfusion liquid can be reliably supplied into the catheter, at a predetermined flow rate, and also provide a catheter-securing member which allows the catheter to be easily and firmly secured to the skin.

More specifically, according to the present invention, a securing member is provided which allows the catheter to be firmly secured to the surface of the skin, and which is constituted by a cylindrical body having a hollow portion into which the catheter body is slidably inserted in its axial direction, the cylindrical body having a slit formed to extend along the axial direction of the cylindrical body, and the slit reaching the hollow portion. Furthermore, according to the present invention, a catheter assembly is provided by mounting such a catheter-securing member on

the catheter.

This invention can be more fully understood from the following detailed description when taken in conjunction with the accompanying drawings, in which:

5 Fig. 1 is a perspective view of a catheter-securing member according to the present invention;

 Fig. 2 is a perspective view of a state wherein the catheter-securing member in Fig. 1 is mounted on the catheter body;

10 Fig. 3 is a perspective view showing a modification of the catheter-securing member according to the present invention; and

 Figs. 4 and 5 are respectively perspective views showing other modifications of the catheter-securing member according to the present invention.

15 The present invention will now be described, with reference to an embodiment shown in the accompanying drawings.

 Fig. 1 is a perspective view of catheter-securing member 1 according to the present invention, which is constituted by cylindrical body 3 having hollow portion 2 into which a catheter body is slidably inserted in an axial direction thereof. Slit 4, reaching hollow portion 2, is formed from one end to the other end of catheter-securing member 1, along the axial direction thereof.

20 Catheter-securing member 1 is preferably made of a flexible synthetic resin material, and more preferably made of a material having a high elasticity. Examples of such a material are a soft vinyl chloride resin, rubber (e.g., silicone rubber and latex rubber), polypropylene, polyethylene, and polyurethane. The length of member 1 is not limited, but is preferably 3 to 30 mm, and more preferably 5 to 15 mm, to ensure secure tying of a ligature on member 1, and ease of handling.

35 Slit 4 may extend along the axial direction of the

catheter body, or it may extend parallel, at an oblique angle, or spirally in relative to the axial direction of the catheter body, and preferably be arranged parallel to the axis of the catheter body. Slit 4 may be formed by simply cutting member 1. Member 1 is fitted on the catheter body, and this cut portion serves as slit 4. Slit 4 may have a predetermined width. If member 1 is fitted on the catheter body and the width of slit 4 is not more than $1/5$ or preferably not more than $1/10$ the overall circumferential length of member 1, the cavity of the catheter body will not be narrowed upon tying by the ligature.

The inner diameter of hollow portion 2 is slightly larger than the outer diameter of the catheter body, so that the catheter body can be moved therewithin. The difference in diameter between them may be determined such that when the catheter-securing member is tied with the ligature, to be fixed to the skin, it is brought into tight contact with and is firmly secured to the catheter body. The inner diameter of hollow portion 2 may alternatively be equal to or slightly smaller than the outer diameter of the catheter body. In this case, the catheter body can be rendered movable by enlarging slit 4.

Catheter-securing member 1 is indwelled, as is shown in Fig. 2, by inserting a predetermined portion of catheter body 5 into hollow portion 2. The position of catheter body 5 is shifted and adjusted within hollow portion 2, so as to determine the portion thereof to be tied with the ligature; in this way catheter-securing member 1 is fixed to the skin.

Catheter body 5 is a tube whose distal and proximal ends are open, and is made of a soft resin. Examples of the soft resin which can be used are silicone rubber, a soft vinyl chloride resin, and a polyurethane elastomer.

In the conventional IVH catheter, a catheter body

having an inner diameter of 0.5 to 1.7 mm and an outer diameter of 0.9 to 2.1 mm is used.

Fig. 3 shows a modification according to the present invention, wherein means for preventing movement of the ligature is arranged. More specifically, annular groove 6 is circumferentially formed to traverse an axial direction of cylindrical body 3, and is preferably formed in a direction perpendicular to the axial direction thereof.

Annular groove 6 need not necessarily be formed around the entire circumferential surface of member 1, but may be formed on a portion thereof, so long as it can prevent the ligature from being moved. Annular groove 6 may be formed in a V-shape, a U-shape, or any other shape. At least two ribs, 7a and 7b, may be circumferentially formed in place of annular groove 6, to extend along a portion of the outer surface of member 1, such that a groove is formed between the ribs.

As is shown in Fig. 5, flat portion 8 is preferably formed at a portion of the outer surface of member 1, such that it extends along the axial direction thereof. A contact area of member 1 to the skin of human body is increased by forming flat portion 8, thereby allowing member 1 to be easily and firmly secured to the skin.

In the case of the modification shown in Fig. 5, in place of annular groove 6, a pair of notches 9 for preventing the ligature from being moved are formed at portions of both the edges of flat portion 8.

The same reference numerals in Figs. 3 to 5 denote the same parts as in Fig. 1, and a description thereof will be omitted.

When a catheter-securing member according to the present invention is used for securing a catheter, for example in the case of an IVH catheter, a distal end of catheter body 5 is inserted into a vein, by means of the hollow needle method, and member 1 is shifted to

a position where it can be secured to a portion of skin. The catheter is then secured in place, by means of ligature tied at a portion of member 1. Then, a high-calorie transfusion liquid is allowed to flow from a proximal end of catheter 5.

The catheter-securing member according to the present invention serves as a member for-securing the catheter body to the skin. Since the catheter-securing member has an insertion portion for the catheter body, and can be moved along the axial direction thereof, the catheter body can be easily and firmly secured to the skin without being bent at a ligature portion or the cavity thereof being narrowed.

The catheter-securing member according to the present invention is not limited to the IVH catheter-securing member, but can be applied to any catheter which is indwelled in a body for a relatively long period of time.

Next, examples and a comparative example according to the present invention will be described.

Example 1

A catheter composed of a soft vinyl chloride resin was constructed, having an outer diameter of 1.5 mm and an inner diameter of 0.8 mm, and having open distal and proximal ends. A catheter-securing member was made of a soft vinyl chloride resin was constructed in the form of a cylindrical tube having an inner diameter of 1.4 mm, an outer diameter of 3.0 mm, and a length of 6.0 mm, and having a slit in its axial direction. A catheter body was inserted into the catheter-securing member, so as to form the catheter according to the present invention. It should be noted that the above catheter-securing member could be easily moved in its axial direction.

The above-described catheter was tied to a rubber plate having a thickness of 6 mm, by using a No. 3 ligature at a portion of the catheter-securing member.

As a result, the catheter body could be easily and firmly secured to the rubber plate by means of the securing member. Furthermore, the catheter body was not bent and a cavity thereof was not narrowed
5 upon fastening of the ligature around the catheter, nor did the catheter break off when it was pulled hard.

Example 2

10 In this example, a catheter was arranged in the same manner as described in Example 1, except that an annular groove (a V-shaped groove having a depth of 0.5 mm) was circumferentially formed in a direction perpendicular to the axis of the catheter-securing member.

15 As was the case in Example 1, the catheter-securing member could be easily moved along the longitudinal axis of the catheter body.

20 The catheter was tied to a rubber plate having a thickness of 6 mm, by using the No. 3 ligature in the same manner as in Example 1, such that the ligature was fitted into the annular groove of the catheter-securing member.

25 As a result, the catheter body could be easily and firmly secured to the rubber plate, by the fixing member. Furthermore, the catheter body was not bent and the cavity thereof was not narrowed upon fastening of the ligature around the catheter, nor did the catheter break off when it was pulled hard. The ligature was not shifted when only the fixing member was
30 pulled.

Example 3

35 A catheter made of a soft vinyl chloride resin was constructed, having an inner diameter of 1.4 mm, a length of 6.0 mm, and an outer diameter of 3.0 mm at a thin wall portion. A flat portion having a length of 6.0 mm in the axial direction of the catheter-securing member and a length of 4.0 mm in a direction

perpendicular to the axial direction thereof was formed on the securing member. A number of 0.8-mm deep notches were formed midway along the flat portion, at positions symmetrical about the axis of the securing member.

A catheter body as shown in Example 1 was used in this example. As was the case in Example 1, the catheter-securing member could be easily moved along the longitudinal axis of the catheter body.

The catheter was tied to the rubber plate having a thickness of 6 mm, by using the No. 3 ligature in the same manner as in Example 1, such that the ligature was fitted into the annular groove of the catheter-securing member. As a result, the catheter body could be easily and firmly secured to the rubber plate, by means of the securing member. Furthermore, the catheter body was not bent and the cavity thereof was not narrowed upon fastening of the ligature around the catheter. The catheter did not break off when it was pulled hard, nor did the ligature shift when only the catheter-securing member was pulled. It should be noted that in this example, the catheter-securing member was secured to the rubber plate more firmly than in the above examples.

Comparative example

In this example, a catheter made of a soft vinyl chloride resin was constructed, having an outer diameter of 1.5 mm and an inner diameter of 0.8 mm, and having open distal and proximal ends. The catheter was tied to the rubber plate having a thickness of 6 mm, by using the No. 3 ligature in the same manner as in Examples 1 to 3.

As a result, the cavity of the catheter was narrowed and the catheter body was bent at the ligature portion when it was sutured somewhat tightly. In addition, the catheter broke at the ligature portion when it was pulled hard.

Claims:

1. A catheter-securing member (1) for securing a catheter body (5) to a surface portion of human skin, comprising:

5 a cylindrical body (3) having a hollow portion (2) into which said catheter body (5) is slidably inserted in an axial direction of said cylindrical body (3), said cylindrical body (3) having a slit (4) formed to extend along the axial direction of said cylindrical body (3), and said slit (4) reaching said
10 hollow portion (2).

2. A member according to claim 1, characterized in that a flat surface is formed on a portion of an outer surface of said cathode-securing member (1), in the axial direction thereof.

15 3. A member according to claim 1, characterized in that said member (1) is made of a flexible material.

4. A member according to claim 3, characterized in that an inner diameter of said hollow portion (2) is slightly smaller than an outer diameter of said catheter
20 body (5).

5. A member according to claim 1, characterized in that a groove (6) is formed on at least a portion of an outer surface of said cylindrical body (3), so as to extend in a direction traversing an axial direction of
25 said cylindrical body (3).

6. A member according to claim 1, characterized in that not less than two projections are formed on at least a portion of an outer surface of said cylindrical body (3), so as to extend in a direction traversing the
30 axial direction of said cylindrical body (3).

7. A catheter assembly comprising:
a catheter body (5); and
a catheter-securing member (1) for securing said catheter body (5) to a surface portion of human skin,
35 said catheter-securing member (1) being constituted

by a cylindrical body (3) having a hollow portion into
which said catheter body (5) is slidably inserted in
an axial direction of said cylindrical body (3), with
a slit (4) being formed to extend along said cylindrical
5 body (3), said slit (4) reaching said hollow portion
(2), and said catheter body (5) being inserted into said
hollow portion (2).

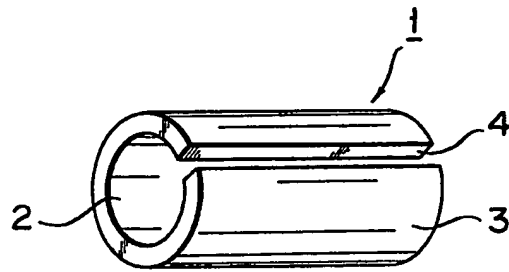


FIG. 1

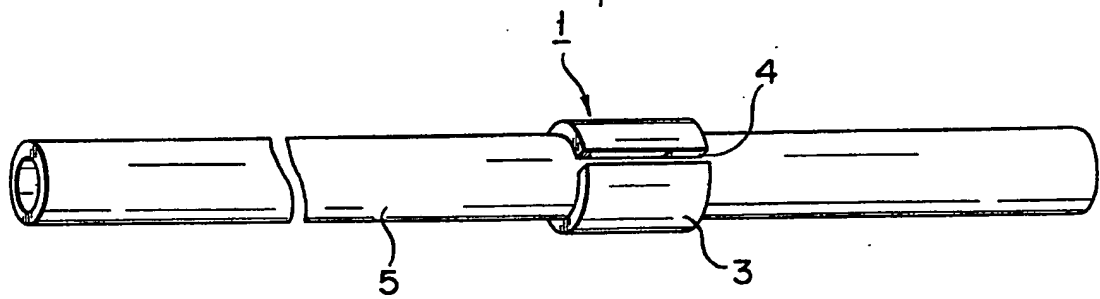


FIG. 2

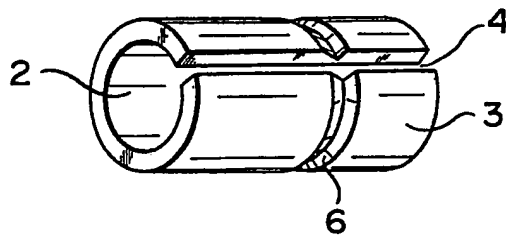


FIG. 3

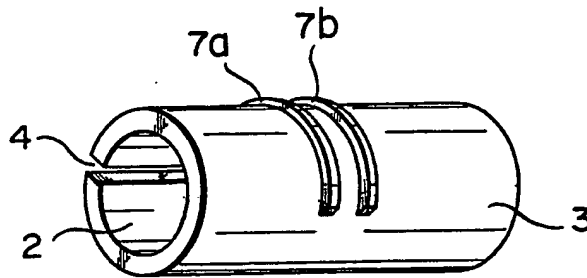


FIG. 4

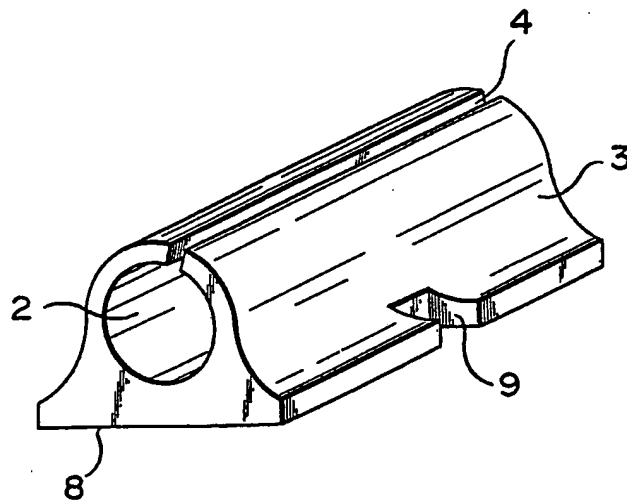


FIG. 5